October 2017

Honorable Scott Pruitt
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Protecting Public Health by Finalizing EPA's Proposed Risk Reduction Rules under TSCA

Dear Administrator Pruitt:

The undersigned groups are deeply concerned by reports that EPA may delay final action on its proposed rules for trichloroethylene (TCE), methylene chloride (MC) and N-methylpyrrolidone (NMP) under section 6(a) of the amended Toxic Substances Control Act (TSCA). If these rules are delayed, more than two million workers and consumers will be needlessly exposed to serious, well-documented health risks. We urge you to keep the rulemaking process moving forward and finalize the three rules as proposed as soon as possible.

Congress overhauled TSCA last year in direct response to EPA's abysmal record in addressing unsafe chemicals under section 6. The new law removes the roadblocks to effective regulation that had stymied the Agency under the old law, which allowed it to issue just a handful of rules under section 6 in more than 40 years. Under TSCA as amended in 2016, EPA now has the tools it needs for forceful action to eliminate unacceptable chemical risks.

If EPA fails to complete its rulemakings on TCE, MC and NMP despite the overwhelming evidence of unreasonable risk, the new risk reduction authorities in TSCA will be rendered ineffective and the work of Congress and many stakeholders to revitalize the TSCA program will go for naught.

THE TARGETED USES OF TCE, MC AND NMP POSE SERIOUS HEALTH RISKS TO A LARGE SEGMENT OF THE POPULATION

The case for action on the three chemicals under section 6 is compelling:

- TCE has been shown to cause cancer, risks of cardiac malformations to fetuses and infants, liver and kidney damage and damage to the nervous system. MC is known to cause asphyxiation from acute exposure and is responsible for 50 reported deaths (and probably many more that are unreported or attributed to other causes) as well as incapacitation, loss of consciousness, and coma. Like TCE, MC is likely to be carcinogenic in humans. And NMP exposure is associated with developmental harm, including increased fetal and postnatal mortality, fetal body weight reductions and other effects on the mother and fetus.
- EPA's proposed rules target high exposure uses that put large segments of the population at risk. By the Agency's estimate, the TCE applications it proposes to ban – aerosol degreasing and spot removal during dry cleaning and vapor degreasing – result in more than 300,000 workers and consumers being exposed to TCE, including men and women of child-bearing age at risk of birth defects and reproductive harm. EPA projects that roughly 32,000 workers and 1.3 million consumers breathe MC each year during paint and coating removal. These uses also account

for inhalation by and dermal exposure to NMP for roughly 30,300 workers and 732,000 consumers each year, including numerous women of childbearing age.

- The uses of these chemicals targeted by the proposed rules are largely uncontrolled and exposure levels are significant. According to EPA's risk assessments, under most use conditions, exposure results in elevated risks of cancer and non-cancer effects well in excess of the benchmarks that EPA has historically used to establish the need for regulatory action.

EPA's proposals explicitly conclude that, based on these factors, the three chemicals present "unreasonable risks of injury" – a conclusion that obligates EPA to take action to eliminate the risk under TSCA.

A DELAY IN REGULATION WOULD BE IRRESPONSIBLE AND DANGEROUS TO PUBLIC HEALTH

Industry has nonetheless urged EPA to withdraw the pending proposals and defer any action while it addresses a broader set of TCE, MC and NMP uses as part of its initial 10 risk evaluations under TSCA section 6(b)(2). However, even if EPA meets the deadlines in the new law, these evaluations and subsequent rulemakings will take another 6 years. Delaying action for this period would have serious public health consequences. Just within the last few months, yet another death has been reported as a result of the use of MC paint removers for bathtub refinishing. More such tragic and avoidable incidents can be expected if these products remain unregulated for several more years. Given the compelling threats to health documented in the three proposals, there is no excuse for delay. To conduct yet another evaluation of the risks of the targeted uses of the three chemicals at the cost of several years of inaction would be irresponsible.

AFTER UNUSUALLY EXTENSIVE STUDY AND PEER REVIEW, FURTHER SCIENTIFIC ASSESSMENT IS UNNECESSARY

Although industry persists in attacking the scientific basis for the EPA risk assessments, few chemicals have been studied as extensively and assessed as rigorously as TCE and MC. EPA's assessments have been subjected to an unusually extensive level of peer review and public comment and their key findings have been consistently affirmed by experts within and outside the Agency.

TCE is a case in point. The Agency first issued a draft assessment for TCE under its Integrated Risk Information System (IRIS) program in 1989. Another draft in 2001 was followed by two rounds of external peer review by the Agency's independent Science Advisory Board (SAB), a report by the National Academy of Sciences (NAS), multiple opportunities for public comment, extensive interagency review, issuance of yet another draft in 2009 and ultimately a final IRIS assessment in 2011. The TSCA risk assessment on TCE incorporated the IRIS findings and was itself subjected to peer review and public comment before being finalized in 2014, 25 years after the initial IRIS draft.

Throughout this lengthy process, industry repeatedly objected to EPA's reliance on the Johnson et al (2003) study demonstrating fetal heart malformations following TCE exposure but these criticisms were fully examined and rejected. In 2011, the SAB upheld EPA's use of the Johnson study despite multiple industry submissions and EPA followed the SAB's advice in its final IRIS assessment later that year. EPA's 2013 draft TSCA assessment built on the IRIS findings and, after a largely favorable peer review, these findings were reaffirmed in the Agency's final assessment in 2014. EPA's analysis of the Johnson study was further explained in a published article by several EPA scientists in 2016. On three occasions in

2013, 2015 and 2016, industry attacked the Agency's reliance on the Johnson study in Requests for Correction (RFCs) under the Information Quality Act (IQA), but EPA issued detailed denials of these requests.

EPA's finding that TCE is a human carcinogen was likewise challenged by industry but was affirmed repeatedly during the peer review process and reinforced by the conclusions of other authoritative bodies. In its 2011 review of EPA's draft IRIS assessment, the SAB "agreed with EPA's conclusion that TCE is considered to be "Carcinogenic to Humans" by all routes of exposure, based on convincing epidemiological evidence of a causal association between TCE exposure and kidney cancer, compelling evidence for lymphoma, and limited evidence for liver cancer." The 2014 TSCA risk assessment adopted these IRIS findings after further peer review and public comment. The International Agency for Research on Cancer (IARC) likewise concluded in 2014 that there is sufficient evidence in humans for the carcinogenicity of TCE and the National Toxicology Program (NTP) determined that TCE is reasonably anticipated to be a human carcinogen in 2015. Industry has twice objected to EPA's carcinogenicity findings under the IQA, to no avail.

EPA's TSCA risk assessment for MC is the product of an equally robust scientific process. The Agency issued its first IRIS assessment in 1988 and in 1995 classified MC as a probable human carcinogen. The IRIS assessment was updated starting in 2009 and a revised assessment was issued in 2011. Independent peer reviews of EPA's findings occurred throughout the IRIS process and again during development of the TSCA Workplan assessment. MC's carcinogenicity has been reviewed and confirmed by multiple bodies, including CPSC, OSHA, NIOSH, FDA and state agencies. State regulators and the European Union (EU) have restricted MC use in paint removal based on its documented risks, showing leadership that thus far has not been exercised by EPA.

After years of exhaustive analysis and extensive peer review, it's time to close the book on the health effects of MC and TCE and move to action. Further scientific assessment would be an extreme case of paralysis by analysis and serve only to advance industry's goal of protecting profits by prolonging scientific controversy on issues that have long been settled.

EPA'S PROPOSALS PROVIDE COMPELLING EVIDENCE THAT BANNING THE TARGETED USES OF THE THREE CHEMICALS IS THE ONLY REMEDY THAT WILL PROTECT PUBLIC HEALTH

EPA's rulemaking record demonstrates that any action short of a ban of the targeted uses of the three chemicals would provide inadequate public health protection and fail to achieve the new law's goal of eliminating risks that EPA finds to be unreasonable. The proposals painstakingly demonstrate that labeling, warnings, protective equipment such as respirators, process controls and changing product formulations – alone or in combination – would be insufficient to reduce worker and consumer risks to acceptable levels. They also demonstrate that technically and economically acceptable substitutes are available or being developed and the costs of substitution are relatively small. Not surprisingly, EPA has concluded that bans of the targeted uses will achieve greater health benefits at lower cost than less effective remedies. Indeed, in the case of the two TCE proposals, the Agency found that benefits would be $32-$477 million annualized, significantly greatly than annualized costs of $4.5-$25 million (even without considering reductions in risks of birth defects which could not be assigned a dollar value). A favorable ratio of benefits to costs is universally considered a compelling basis for regulation.

In sum, failure to finalize the three section 6(a) proposals would callously prolong serious and widespread risks to public health that EPA has fully analyzed and documented. Delay would serve no purpose beyond the business interests of the companies that produce and distribute the three chemicals. The record demonstrates that the costs of regulation are small but the benefits are great. We urge you to issue final rules banning the targeted uses of TCE, MC and NMP as soon as possible.

Sincerely yours,

Alaska Community Action on Toxics
Alliance of Nurses for Healthy Environments
Asbestos Disease Awareness Organization
Barron Park Association Foundation
Berkshire Environmental Action Team, Inc. (BEAT)
Breast Cancer Action
Breast Cancer Prevention Partners
Center for Environmental Health
Center for Public Environmental Oversight
Citizens Campaign for the Environment
Citizens For A Clean Pompton Lakes
Clean Production Action
Clean Water Action
Clean Water Action California
Clean Water Action Connecticut
Clean Water Action Minnesota
ConnectiCOSH
Connecticut Nurses' Association
Conservation Minnesota
CT Citizens Action Group
CT Coalition for Environmental Justice
Earthjustice
Ecology Center
Environmental Health Strategy Center
Health Care Without Harm
Healthy Building Network
Healthy Legacy Coalition
League of Conservation Voters
Learning Disabilities Association of America
Learning Disabilities Association of Arkansas
Learning Disabilities Association of Georgia
Learning Disabilities Association of Illinois
Learning Disabilities Association of Maine
Learning Disabilities Association of Minnesota
Learning Disabilities Association of New York State
Learning Disabilities Association of Oklahoma
Learning Disabilities Association of South Carolina
Learning Disabilities Association of Wisconsin
Maryland PIRG
Massachusetts Breast Cancer Coalition
Midwest Environmental Justice Organization
Midwest Pesticide Action Center
Natural Resources Defense Council
NC Child
North Carolina Conservation Network
Physicians for Social Responsibility
Projects for Environmental Health, Knowledge, & Action (PEHKA)
Safer States
Science and Environmental Health Network
Texas Campaign for the Environment
The Arc Greater Twin Cities
The Lands Council
Toxic-Free Future
U.S. PIRG
UPSTREAM
Vermont Conservation Voters
Vermont Public Interest Research Group (VPIRG)
Voluntary Cleanup Advisory Board
WE ACT for Environmental Justice
Women for a Healthy Environment
Women's Voices for the Earth
Women's Environmental Institute